GDUFA Reauthorization Stakeholder Meeting
December 15, 2020, 12:00 pm – 1:00 pm
Virtual Meeting

Purpose
The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA hold monthly discussions with representatives of patient and consumer advocacy groups on their views on the reauthorization of GDUFA and their suggestions for changes to the GDUFA program. These discussions are to take place at least once every month during the GDUFA reauthorization negotiations between FDA and the generic drug industry.

Participants

FDA		Stakeholders
Tiana Barnes	CDER	Karin Bolte - American Pharmacists Association
Carter Beach	CDER	Jeanette Contreras - National Consumers League
Ashley Boam	CDER	Rutesh Dave – National Institute for Pharmaceutical Technology and Education (NIPTE)
Jacqueline Corrigan-Curay	CDER	Vadim Gurvich - NIPTE
Alonza Cruse	ORA/FDA	Xiuling Lu - NIPTE
Dat Doan	CDER	Kenneth Morris - NIPTE
Robert Lionberger	CDER	Sohail Mosaddegh – U.S. Pharmacopeia
Susan Rosencrance	CDER	Fernando Muzzio - NIPTE
Tawni Schwemer	CDER	Rex Reklaitis - NIPTE
Edward (Ted) Sherwood	CDER	Rick White – National Organization for Rare Disorders (NORD)
Maryll Toufanian	CDER	

Welcome and Overview
Following introductions, FDA provided a summary of negotiations between FDA and industry held on November 19, December 3, and December 10, 2020.

Stakeholder Comments
Representatives from NIPTE provided the following presentations:

1. "New prior knowledge for Generic and Repurposed Products" - Professor Kenneth Morris
2. "Facilitating implementation of advanced manufacturing systems for generic companies" - Professor Fernando Muzzio

Next Meeting
The next stakeholder meeting is planned for Tuesday, January 26, 2021.